The opinion in support of the decision being entered today is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALBERT M. FLEISCHNER

Appeal 2007-1615
Application 10/693,442
Technology Center 1600

DECIDED: September 27, 2007

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134 from a final rejection of claims 1, 2, 7, 35, and 36. The Examiner has rejected the claims as unpatentable under 35 U.S.C. § 103(a).[1] We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Written description and enablement rejections of the claims under the first paragraph of 35 U.S.C. § 112 have been withdrawn (Answer 4).

DISCUSSION

"The *Hoodia gordonii* cactus has been used safely and effectively for decades to temporarily stave off hunger and thirst" (Spec. 2). According to Appellant, "temporary or opportunistic use appears . . . to cause a long-term *increase* in body mass" (*id.* at 3) because "one-time administration creates a transient appetite suppression phase . . . followed by an appetite stimulation phase of indeterminate duration" (*id.* at 5).

Nevertheless, Appellant teaches that *Hoodia gordonii* "can be used to safely and effectively control obesity . . . [by regulating] *the timing* of the *hoodia* administration" (*id.* at 4). In particular, Appellant "propose[s] repeat administration, before the onset of the appetite stimulation phase. In other words, [ ] administration [that] occurs at least as frequently as the length of the appetite suppression phase" (*id.* at 5), "over an extended period of time . . . enabl[ing] the user's body to adjust to a lower basal body weight" (*id.* at 6).

Claims 1, 2, 7, 35, and 36, the only claims at issue in this appeal,[2] are as follows:

1. A method of body weight reduction, comprising administering to a human in need thereof a body weight reducing amount of *hoodia gordonii* at least once every about 48 hours, for at least about 45 days.

2. The method of claim 1, said *hoodia gordonii* administered at least three times every 24 hours.

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[2] Claims 3-6, 17-26, 28-34, and 37-40, are also pending, but have been indicated allowable (Answer 3). Claims 8-16 and 27 have been canceled (Br. 1).

7. The method of claim 2, comprising administering from about 5 to about 200 milligrams of *hoodia gordonii*, together with from about 50 to about 200 micrograms of chromium, from about 10 to about 50 micrograms of vanadium, 0 to about 400 milligrams of glucomannan, from about 25 to about 200 milligrams of sodium carboxymethylcellulose, 0 to about 15 milligrams of citrus naringinine, 0 to about 200 milligrams of glucosamine, 0 to about 500 milligrams of cocoa PEA standardized extract, and 0 to about 250 milligrams of green tea extract.

35. A method of body weight reduction, comprising administering to a human in need thereof *hoodia gordonii* in an amount sufficient to suppress the appetite after said administration, said administration repeated a plurality of times, each one of said times occurring before said *hoodia gordonii* causes an appetite stimulating effect.

36. The method of claim 35, said *hoodia gordonii* administered at least three times every 24 hours.

The Examiner relies on the following references:

Van Heerden	US 6,376,657	Apr. 23, 2002
Fleischner	US 6,420,350	Jul. 16, 2002

Tulp et al., *Effect of Hoodia Plant on Food Intake and Body Weight in Lean and Obese LA/Ntul//-cp Rats*, 15 FASEB Journal A404 (March 7, 2001).

Barnett, *In Africa the Hoodia Cactus Keeps Men Alive. Now Its Secret is 'Stolen' to Make Us Thin*, The Observer (June 17, 2001).

Habeck, *A Succulent Cure to End Obesity*, 7 Drug Discovery Today 280-281 (March 2002).

Kahn, *Prickly Dispute Finally Laid to Rest: San Reach Agreement with CSIR Over Use of Appetite-Suppressing Cactus*, Business Day (Johannesburg) (March 22, 2002).

Obviousness

I. Claims 1, 2, 35, and 36 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Tulp, Barnett, Habeck, Kahn, or Van Heerden.

Tulp teaches that "[c]onsumption of the [South] African Hoodia plant has been used for many years to control appetite in humans" (Tulp, Abstract). "To determine the effects of Hoodia sp. on food intake [ ] and body weight [ ], groups of young adult male lean and obese LA/Ntul//-cp rats were administered a dehydrated crude homogenized preparation obtained from . . . Hoodia [sp.] or fed normally (controls)" (*id.*). "Spontaneous [food intake] decreased by < 50% within 2h of administration of crude plant mixture or extract" and "[a]d libitum administration (< 3 w.) resulted in sustained decrease in voluntary [food intake] in lean and obese rats and with marked reduction in [body weight] (< 100 g/rat) in obese and moderate reduction (< 50 g/rat) in lean rats, while control rats fed normally gained [body weight] normally" (*id.*). Tulp concluded that "these results indicate that Hoodia sp. may have strong potential for clinical appetite regulation and weight control" (*id.*).

Both Kahn and Barnett report that P57, the appetite-suppressing ingredient in the *Hoodia* cactus, has been isolated and patented.

Habeck teaches that extracts from the *Hoodia* plant have been shown to be "highly effective in reducing weight" (Habeck 280), and that P57, the active ingredient in *Hoodia*, "produced a significant weight loss and had a good safety profile in a variety of preclinical studies using rats, mice and dogs" (*id.*). The results of a "proof-of-principle" study in humans were consistent with the results observed in animals. "60 patients took part in [a]

double blind, placebo controlled study. During the first two-stages of the study . . . the safety, tolerability and pharmacokinetics of ascending single doses [of P57] and of repeated dosing in healthy overweight volunteers [were assessed]" (*id.*). "In the third phase, . . . the effects on calorie intake in [ ] overweight men who took the compound or placebo twice daily for 15 days [were investigated]" (*id.*). "By the end of the study, men in the treatment group achieved a 30% reduction in calorie intake, accompanied by a significant reduction in body fat content by 1 kg" (*id.*). Habeck reports that an independent consultant, responsible for advising researchers on the dietary aspects of their clinical trials "agree[d] that the results of the proof-of-principle study are very encouraging" and suggested "longer studies in more people to demonstrate that this is a consistent effect[,] [since] [o]besity is a chronic relapsing problem" (*id.*). Habeck also reports that the researchers' "next step will be to look at the dosing interval" (*id.*).

Van Heerden describes appetite suppressing extracts of *Hoodia*, a pharmaceutical composition containing P57, a compound from the *Hoodia* plant responsible for appetite suppression, and derivatives and analogs of P57. Test rats given a single dose of an extract of *Hoodia* "on day 5 [of an experiment described in Examples 1 and 2] displayed a substantially diminished food intake over the next two days, while the control group did not disclose a comparable reduced food intake. The food intake of the test group returned to normal, and in fact increased from day 8 onwards" (Van Heerden, col. 37, l. 50 to col. 38, l. 4). In other words, the appetite suppressive effect of a single dose lasted 2 to 3 days, after which appetite

rebounded. No data on body mass gain or loss were provided for the experiments discussed in Examples 1 and 2.

However, in several other experiments, Van Heerden showed that the appetite suppressive effect of *Hoodia* is associated with reductions in body weight or decreased growth rate when compared to controls. For example, in Example 44, an eight day study, *Hoodia* sap (Sample 1), administered orally, "produced marked, dose-related reductions in daily food consumption[,] [and] [t]he duration and amplitude of these reductions . . . were dose-dependent . . . The highest dose of Sample 1 (sap) produced statistically significant reductions in food consumption on a daily basis up to 5 days post-dose" (Van Heerden, col. 58, ll. 18-27). "Sample 1 (pure sap) [also] produced dose-related, statistically significant effects on bodyweights when compared with the vehicle-treated control group . . . These effects were statistically significant from 48 hours post-dose until the end of the study" (*id.* at col. 58, ll. 46-53). Spray dried sap (Sample 2), also "produced marked and statistically significant reductions in food consumption . . . [which] lasted 48 hours post-dose" (*id.* at 58, ll. 28-31), and "statistically significant reductions in growth of the animals when compared with the vehicle-treated control group . . . These effects were statistically significant between days 3 (48 hours post-dose) and 5 inclusive" (*id.* at 58, ll. 54-59).

The Examiner acknowledges that the "references do not expressly teach the time periods/intervals instantly claimed" (Answer 15). However, the Examiner argues that the cited references "teach that the cactus plant *Hoodia gordonii* (and/or extracts thereof - such as the sap: as disclosed in [Van Heerden]) is effective as a weight loss and/or anti-obesity agent for

losing weight when orally administered" (Answer 5), and contends that "[t]he adjustment of particular conventional working conditions - e.g., determining appropriate, suitable time periods and intervals for orally administering [ ] a *Hoodia gordonii* weight-loss product - is deemed merely a matter of . . . routine optimization which is well within the purview of the skilled artisan, especially given that the skilled dietary artisan would clearly take into account the amount of weight an overweight/obese subject needs to lose and administer such a weight-loss product accordingly - e.g., on a commonly-employed once or more daily basis for an extended period of time (as instantly claimed) so as to achieve a desired amount of weight loss/reduction in the . . . subject" (*id.* at 5-6).

We agree with the Examiner. All of the references relied on by the Examiner discuss the appetite suppressive effect of the *Hoodia* plant and its extracts, and Tulp, Habeck, and Van Heerden, at the very least, teach that *Hoodia*'s appetite suppressive effect facilitates weight loss in animals, including humans (in the case of Habeck). In addition, Van Heerden provides evidence that the appetite suppressive effect of *Hoodia* is temporary, and the appetite rebounds shortly after administration is ended; thus, one skilled in the art would have found it obvious to continue administration for an extended period of time. Habeck also provides evidence that it would have been obvious for those skilled in the art to administer *Hoodia* for longer periods of time than those used in the clinical trials, since "obesity is a chronic relapsing problem and you need a treatment that is going to work safely and effectively over a long period of time" (Habeck 281). Habeck additionally provides evidence that it would have

been obvious to optimize the dosing interval based on empirical observation. Indeed, Habeck indicates that "the next step will be to take a look at dosing intervals" (*id.*).

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). "Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed" (*id.* at 1740-41).

We find that the Examiner has established that the combined teachings of the cited references, all of which pertain to the appetite suppressive effects of the *Hoodia gordonii* plant, and at least some of which correlate that appetite suppressive effect with weight loss, would have provided a reason for one of ordinary skill in the art to administer *Hoodia*

for an extended period of time, and to adjust the dosage to prevent the appetite from rebounding for the duration of the treatment period.

We have carefully considered all of Appellant's arguments, but are not persuaded otherwise.

In particular, Appellant argues that the Examiner equates appetite suppression and weight control, but "one of skill in the art would recognize that the two concepts are not coterminus" (Appeal Br. 12). Relying on the Declaration of Albert M. Fleischner (dated December 21, 2005, hereinafter "Decl. I"), Appellant argues that "[i]t is possible to cause weight loss without suppressing appetite" and "it is possible to suppress appetite without causing weight loss" (Appeal Br. 13), thus, "appetite suppression may have no effect on body weight" (*id.* at 14). We do not disagree, but the distinction is of no consequence in the present case because, as discussed above, the references cited by the Examiner teach that the appetite suppressive effect of *Hoodia* can indeed facilitate weight loss.

In a similar vein, Appellant argues that "[a]ppetite suppression . . . may cause weight *gain*" (Appeal Br. 14). Appellant cites Blundell[3] for the proposition that food, "the most widely-used appetite suppressant in the world can also cause weight gain" (*id.*). We are not persuaded. Again, the references cited by the Examiner establish that *Hoodia* can suppress appetite while reducing food intake, i.e., calorie intake, at the same time, and can facilitate weight loss.

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[3] Blundell, "*Pharmacological Approaches to Appetite Suppression*," 2 Trends in Pharmacol. Sci. 147157 (1991).

Appellant argues that Van Heerden "teaches a reasonable expectation not of success, but of *failure*" (Appeal Br. 18), because Van Heerden's data shows that the active ingredient in *Hoodia* "suppresses appetite transiently, then stimulates appetite" (*id.* at 15), which "causes marked *weight gain*" (*id.*). Appellant cites Van Heerden's Figures 5 and 6 in support of this contention. Figures 5 and 6 represent data from Example 45, and they do show some inconsistencies - some animals given certain extracts lost body mass, while some gained. However, Van Heerden states that

> [a]nimals in this study received a restricted diet i.e. animals only received food between 12:00 and 3:00 pm daily. This is different from all other biological assays conducted thus far, whereby food was available to the rats a[d] lib. Animals were acclimati[z]ed over a seven day period (days -7 to -1), dosing took place from day 0 to day 6 at 9:00 am by oral gavage . . .
>
> The results generated during the study showed that the acclimatization period was too short. Rats feed mainly during the night and the sudden change to a restricted access to feed for three hours during day-time, resulted in low daily feed intakes. The daily intake of feed was still increasing in most groups at the end of the acclimatization period when dosing with the test items started. As a result of this, the effect of the test materials did not significantly affect the food intake of the rats during the period of dosing.

Van Heerden, col. 63, l. 53 to col. 64, l. 57. In other words, Van Heerden acknowledges that this particular experiment was flawed. Therefore, we find that the data shown in Figures 5 and 6 do not support Appellant's contention that "hoodia extracts cause body mass to increase, not decrease" (Decl. I, ¶ 17). Indeed, as discussed above, Van Heerden's Example 44 shows just the opposite.

Appellant also argues that "one of skill in the art would read Habeck to imply that [the active ingredient in *Hoodia*] was not effective to reduce body fat" (Appeal Br. 21) because Habeck "specifically withheld the results of the control group" (*id.* at 20). "Therefore," Appellant argues, Habeck "fails to inform one of skill in the art about whether the body fat change was due to, for example, the prison-like conditions under which test subjects were held, or the bad quality of food which they were given" (*id.*). We do not find this argument persuasive. Habeck's article is a summary of a 15 day double-blind, placebo controlled proof-of-principle study described as "a very demanding clinical study because people had nothing to do but eat and watch TV" (Habeck 280). Habeck does not reproduce the data underlying the summary, but does report that the "men in the treatment group achieved a 30% reduction in calorie intake, accompanied by a significant reduction in body fat content by 1 kg" (*id.*). We do not agree that one of skill in the art would conclude that the active ingredient in *Hoodia* "was not effective in reducing body fat" (Appeal Br. 21), given the premise of the article: *Hoodia* "has shown promise as an appetite suppressant in clinical trials and could have potential as a new anti-obesity drug" (*id.*).

Appellant acknowledges that Tulp concludes that "Hoodia sp. may have a strong potential for clinical appetite regulation and weight control" (Declaration of Albert M. Fleischner, dated March 10, 2006, ¶ 21, hereinafter "Decl. II"), but argues that "one of skill in the art would read this as an invitation to pursue further experimentation" (*id.*), rather than an "assurance of success in humans[,] because LA/Ntul//-cp mutants are so different from normal rats (and from normal human beings)" (Appeal Br.

24). Appellant points out that LA/Ntul//-cp rats used in Tulp's experiments have a number of mutations that result in morbid, early-onset obesity. This argument is not persuasive. First, Appellant does not dispute that the LA/Ntul//-cp rat is a recognized animal model of morbid obesity in humans (*see e.g.,* Decl. II, ¶17). Second, obviousness does not require an assurance of success; on the contrary, only a reasonable expectation of success is required.

Finally, Appellant argues that "[t]he claimed invention has several secondary indicia of non-obviousness" (Appeal Br. 27), specifically, "unexpectedly successful results" and "achieving a new and different function" and "evidence of copying by competitors" (*id.*). With respect to the first two indicia, Appellant has provided a number of Exhibits (clinical trial results, appended to Decl. I), purportedly showing that "*Hoodia gordonii* is effective for weight loss" (Appeal Br. 27), and argues that this result "is not only different from the prior art, but the direct opposite of it" (*id.* at 28). Even accepting that the clinical trials described in the exhibits demonstrate that *Hoodia* is effective for weight loss in humans, we do not agree with Appellant's conclusion that the effect would have been unexpected, or that the prior art would have suggested that *Hoodia* facilitates weight gain when administered in multiple doses. For the reasons discussed above, we do not agree that the prior art teaches that ingesting multiple doses of *Hoodia* results in weight gain, and we find that the prior art of record would have provided one of ordinary skill in the art with a reasonable expectation that *Hoodia gordonii* would facilitate weight loss in humans.

Moreover, we are not persuaded by Appellant's contention that widespread copying of the instant invention is evidence of the present invention's non-obviousness. Appellant points to copies of Appellant's TrimSpa® brand *Hoodia gordonii* weight control product, "sold as TrimSmart™, TrimClub™ and HoodiaSpa™, [which] copied the original TrimSpa® product, the TrimSpa® formula, and used trade marks and trade dress deceptively similar to the original TrimSpa® packaging" (Appeal Br. 29) as evidence of non-obviousness. While we agree that widespread copying may be an indicator of non-obviousness, copying may be attributable to other factors as well. *See e.g., Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015 (Fed. Cir. 1985). In the present case, Appellant has not established that copying is not attributable to others capitalizing on Appellant's advertising campaign and exposure in the market place, particularly as Appellant's trademarks and trade dress were copied in an apparent attempt to pass off the copies as Appellant's TrimSpa® product. Similarly, Appellant points to "a large number of sources advertising *Hoodia* weight loss products for sale . . . includ[ing] . . . www.hoodoba.com, www.weightlossguide.com, www.h57.com, www.hoodithin.com and www.phenterlean.com" (Appeal Br. 30). However, Appellant has not established that these products were not based on disclosures in the prior art, for example, Van Heerden's disclosure of P57.

We find that the Examiner has established a prima facie case that the claimed invention would have been obvious over the cited prior art, which Appellant has not overcome by argument or evidence. The rejection of

claims 1, 2, 35, and 36 under 35 U.S.C. § 103(a) as unpatentable over Tulp, Barnett, Habeck, Kahn, or Van Heerden is affirmed.

II. Claims 1, 2, 7, 35, and 36[4] stand rejected under 35 U.S.C. § 103(a) as unpatentable over Tulp, Barnett, Habeck, Kahn, or Van Heerden, in view of Fleischner.

The Examiner relies on Fleischner as disclosing additional "weight-loss compositions comprising conventional art-recognized ingredients commonly employed therein such as glucosamine, caffeine, green tea extract, ma huang (ephedra/ephedrine), chromium, and/or vanadium" (Answer 7), and contends that it would have been obvious to combine *Hoodia* with these additional ingredients "for their known benefit" (*id.*).

Appellant's arguments with respect to this ground of rejection are essentially the same as for the previous rejection, and are not persuasive for the reasons discussed above.

The rejection of claims 1, 2, 7, 35 and 36 under 35 U.S.C. § 103(a) as unpatentable over Tulp, Barnett, Habeck, Kahn, or Van Heerden, in view of Fleischner is affirmed.

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[4] The Examiner listed the claims subject to this rejection as claims 1, 2, 7-9, 35 and 36, but according to Appellant, claims 8 and 9 have been canceled (Br. 1).

SUMMARY

Both rejections of the claims under 35 U.S.C. § 103(a) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

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